DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 12, 2015

Salter labs
Ms. Aurelia Brownridge
Regulatory Associate
2365 Camino Vida Roble
Carlsbad, CALIFORNIA 92011

Re: K142416
Trade/Device Name: Luma Wrap™
Regulation Number: 21 CFR 880.5700
Regulation Name: Neonatal phototherapy unit
Regulatory Class: II
Dated: May 12, 2015
Received: May 13, 2015

Dear Ms. Brownridge:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142416

Device Name
Luma Wrap™

Indications for Use *(Describe)*
To swaddle infants during neonatal phototherapy in the hospital or home setting. Single patient use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Revised

K142416, 510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21 CFR 807.92.

I. SUBMITTER

Salter Labs
2365 Camino Vida Roble
Carlsbad, CA 92011

Phone: (760) 795-7102
Fax: (760) 683-6797

Contact Person: Aurelia Brownridge, Regulatory Associate
Date Summary Prepared: April 13, 2015

II. DEVICE

Proprietary Name: Luma Wrap™
Common Name: Phototherapy infant swaddling blanket
Classification Name: Neonatal Phototherapy Unit
Regulation Number: 880.5700
Regulatory Class: II
Product Code: PDH

III. PREDICATE DEVICE

Little Angels Swaddling Blanket (K123411)
This predicate has not been subject to a design-related recall.
No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The Luma Wrap™ by Beevers Manufacturing & Supply, Inc./Salter Labs is a translucent, highly breathable, phototherapy-compatible, disposable infant swaddling blanket. It is made of spun bond polypropylene non-woven fabric that is more than 90% light-permeable. The Luma Wrap™ provides centered and comfortable boundaries to benefit many babies who exhaust themselves with their hyper-reactive, frantic movements while receiving phototherapy. The Luma Wrap™ is a stand-alone device and has no accessories. It is available in two designs: a square and a shape similar to baseball's home plate. A 2" strip of self-adhesive is an added optional convenience feature to assist the user in positioning the device by adhering two parts of the device together.

V. INTENDED USE / INDICATIONS FOR USE

To swaddle infants during neonatal phototherapy in the hospital or home setting. Single patient use only.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

As shown in **Table 5-1**, the Luma Wrap™ is similar to the predicate device with regards to intended use, indications for use, target patient population, clinical setting, material, skin contact duration, and single-layer light transmittance. The Luma Wrap™ has areas of fabric overlap after wrapping it around the infant. However, the Luma Wrap™ also has a slightly higher single-layer light transmittance and the light transmittances are still quite high for double- and triple-layers of Luma Wrap™ fabric. Furthermore, the Luma Wrap™ Instructions for Use instructs the user to position the adhesive and multiple layers in a location where the infant is receiving the least amount (or no amount) of phototherapy light. The Little Angels Swaddling Blanket has a pocket feature for convenience when using the device in conjunction with light emitting pads. Although the Luma Wrap™ does not have this pocket feature, it offers a different optional convenience feature for all sizes: an adhesive strip for quickly and easily securing the device in place. The adhesive strip is used to secure two parts of the swaddling blanket together.

Table 5-1: Comparison Table, Luma Wrap™ vs. Little Angels Swaddling Blanket

Device	**Little Angels Swaddling Blanket (510(k) #K123411)**	**Luma Wrap™ (this submission)**
Manufacturer	Bionix Development Corporation Toledo, Ohio	Beevers Manufacturig & Supply Inc., / Salter Labs, Carlsbad CA.
Intended Use	Phototherapy-compatible infant swaddling blanket	Phototherapy-compatible infant swaddling blanket
Indications for Use	Infant swaddling during phototherapy	Infant swaddling during phototherapy
Principal of Operation / Mechanism of Action	Fabric allows phototherapy light to pass through to the infant during swaddling	Fabric allows phototherapy light to pass through to the infant during swaddling
Clinical Setting / Sites of Use	Clinical / Hospital Use and Home Use	Clinical / Hospital Use and Home Use
Disposable / Reusable	Disposable device (Single-patient use)	Disposable device (Single-patient use)
Material / Device Composition	Lightweight spun bond nonwoven polypropylene fabric	Lightweight spun bond nonwoven polypropylene fabric
Fabric Weight	15.3 g/m2 (0.45 oz/yd2)	15.0 g/m2 (0.44 oz/yd2)
Manufacturing Process of Device from Material	Die-cut	Die-cut
Skin Contact Duration	Less than 24 hours	Less than 24 hours
Material Between Infant and Phototherapy Source	Single layer	Single layer (for majority of blanket) with some areas of double or triple layers
Material Light Transmittance (Single Layer)	≥90% (90.0% – 91.7%; per 510(k) summary)	≥92% (92.0% – 97.7%; per bench test findings)
Adhesive Strip for Securing Two Parts of Swaddling Blanket Together	No	Yes and No (optional feature)
Pocket for Light Emitting Pad	Yes	No

VII. PERFORMANCE DATA

No performance tests were performed on the Luma Wrap™ in animals or in the clinical setting. However, several performance tests were performed on the bench. Light transmittance tests were performed to demonstrate substantial equivalence to the predicate device. These tests were performed in a laboratory and in an empty hospital room. The light transmittance of the Luma Wrap™ fabric was calculated by measuring the throughput of blue phototherapy light with and without the presence of the fabric. These tests concluded that the light transmittance of a single layer of Luma Wrap™ fabric is slightly higher (92.0% – 97.7%) than the light transmittance of a single layer of the Little Angels Swaddling Blanket (90.0% – 91.7%; per K123411 510(k) summary). Specific findings are listed in **Table 2**.

Table 5-2: Luma Wrap™ Light Transmittance Test Findings (Single-Layer)

Test #	Test Location Light Source	Test Location Light Source	Test Location Light Source	Test Location Light Source
1	Laboratory	Overhead LED light	6” – 18”	92.0%
2	Laboratory	Overhead LED light sources	12”	93.7%
3	Empty hospital room	Overhead phototherapy halogen light source	7.5” – 19.5”	94.0%
4	Empty hospital room	Beneath-the-infant phototherapy fluorescent light source	Not applicable	97.7%

Additional performance tests (pull strength and cycling / reliability) were performed on the adhesive to verify that this optional convenience feature of the Luma Wrap™ met performance specifications. The adhesive pull strength, as measured with a force gauge pulled perpendicular to the adhesive, was, on average, 200g. This adhesive pull strength measurement met the performance specification. The closure reliability / adhesive cycle test verified that the adhesive could be opened and closed at least 20 times. Finally, an air flow resistance bench performance test verified that the Luma Wrap™ fabric did not exhibit substantial resistance to air flow at rates of 1-12 lpm. Specifically, the air flow resistance for two layers of fabric with an air flow of 8 lpm was measured to be 0.066 mmH2O/sq cm. This met the device’s performance specification and confirmed that an infant’s breathing is not impaired if the device slips over the infant’s nose and/or mouth.

VIII. CONCLUSIONS

There are minor differences between the Luma Wrap™ and the predicate device in technological characteristics with regards to fabric weight, material between the infant and phototherapy light source, material light transmittance, and pocket and adhesive convenience features. However, these differences do not raise new questions of safety or effectiveness. Thus, the device characteristics compared in **Table 5-1** and the results of the bench performance tests confirm that the Luma Wrap™ is substantially equivalent to the Little Angels Swaddling Blanket.